

EXHIBIT 1

PART 2

instead of filing a request for continued examination. Of course, applicant may seek by petition a third or subsequent continuation or continuation-in-part application or a second or subsequent request for continued examination.

The Office, however, is implementing an optional streamlined continuation application procedure under which an applicant may request to have a continuation application filed on or after November 1, 2007, placed on an examiner's amended (Regular Amended) docket. The examiner will normally pick up for action a continuation application that has been placed on the examiner's amended (Regular Amended) docket faster (e.g., within a few months from the date the application is docketed) than an application placed on the examiner's new continuing application (New Special) docket. The following conditions must be met for the continuation application to be placed on an examiner's amended (Regular Amended) docket rather than on the new continuing application (New Special) docket: (1) The application must disclose and claim only an invention or inventions that were disclosed and claimed in the prior-filed application; (2) the applicant must agree that any election in response to a requirement to comply with the requirement of unity of invention under PCT Rule 13 or a requirement for restriction under 35 U.S.C. 121, including an election of species requirement, in the prior-filed application carries over to the continuation application; (3) the prior-filed application must be under a final Office action (§ 1.113) or under appeal at the time of filing the continuation application; (4) the prior-filed application must be expressly abandoned upon filing of the continuation application, with a letter of express abandonment under § 1.138 being concurrently filed in the prior-filed application; and (5) applicant must request that the continuation application be placed on an examiner's amended (Regular Amended) docket. This procedure is not applicable to design applicants because the continued prosecution application procedures of § 1.53(d) currently provide design applicants with an optional streamlined continuation application procedure.

The optional streamlined continuation application procedure, however, does require that the applicant provide a continuation application filed under 35 U.S.C. 111(a) and § 1.53(b) (and not a request for continued examination under 35 U.S.C. 132(b)) and

§ 1.114 or a continued prosecution application under § 1.53(d)). Thus, the applicant must file a continuation application that meets the conditions set forth in 35 U.S.C. 111(a) and § 1.53(b) to be accorded a filing date. The continuation application must also be complete under § 1.51(b) or completed under § 1.53(f). The Office will not docket an application for examination until the application is complete (§§ 1.51(b) and 1.53(f)) and in condition for publication (§ 1.211). See § 1.53(h). Thus, any delay in submitting the filing fee and oath or declaration (or copy of the oath or declaration from the prior-filed application under § 1.63(d)) will delay the docketing of a continuation application even if the applicant has requested that the continuation application be given streamlined docketing.

This optional streamlined continuation application procedure concerns only the placement of the continuation application on an examiner's amended (Regular Amended) docket. The continuation application is otherwise treated as a new application for patent. For example, (1) the application filing fees including the basic filing fee, search and examination fees, and any required excess claims fees (and not the request for continued examination fee set forth in § 1.17(e)) are required; (2) the continuation application will be assigned a new application number; and (3) the continuation application is subject to the patent term provisions of 35 U.S.C. 154(b) and § 1.702 *et seq.* as a new continuation application (and not a request for continued examination in the prior-filed application).

Section 1.78(d)(1)(ii) provides for divisional applications of an application for the claims to a non-elected invention that has not been examined if the application was subject to a requirement to comply with the requirement of unity of invention under PCT Rule 13 or a requirement for restriction under 35 U.S.C. 121. The divisional application need not be filed during the pendency of the application subject to a requirement for restriction, as long as the copendency requirement of 35 U.S.C. 120 is met. This final rule also permits applicant to file two continuation applications of a divisional application plus a request for continued examination in the divisional application family, without any justification. See §§ 1.78(d)(1)(iii) and 1.114(f).

Specifically, § 1.78(d)(1)(ii) permits a divisional application of a prior-filed nonprovisional application or international application designating

the United States of America under the following conditions. First, the divisional application must be a divisional application as defined in § 1.78(a)(2) that claims the benefit under 35 U.S.C. 120, 121, or 365(c) of a prior-filed application that was subject to a requirement to comply with the requirement of unity of invention under PCT Rule 13 or a requirement for restriction under 35 U.S.C. 121. Second, the divisional application must contain only claims directed to an invention or inventions that were identified in the requirement to comply with the requirement of unity of invention or requirement for restriction but were not elected for examination and were not examined in the prior-filed application or in any other nonprovisional application. The "not elected for examination and were not examined in any other nonprovisional application" requirement does not apply to any continuation application that claims the benefit under 35 U.S.C. 120, 121, or 365(c) of the divisional application and satisfies the conditions set forth in § 1.78(d)(1)(iii) or (d)(1)(vi).

Section 1.78(d)(1)(ii)(A) permits an applicant to obtain examination of claims that were withdrawn from consideration in the prior-filed application due to a requirement to comply with the requirement of unity of invention under PCT Rule 13 or a requirement for restriction under 35 U.S.C. 121. Thus, § 1.78(d)(1)(ii)(A) permits a divisional application filed as a result of a requirement to comply with the requirement of unity of invention under PCT Rule 13 or requirement for restriction under 35 U.S.C. 121 in the prior-filed application. Section 1.78(d)(1)(ii)(A), however, does not permit a divisional application not filed as a result of such a requirement in the prior-filed application. Thus, § 1.78(d)(1)(ii)(A) permits so-called "involuntary" divisional applications but does not permit so-called "voluntary" divisional applications.

Section 1.78(d)(1)(ii)(B) does not permit the filing of a set of parallel divisional applications containing claims to the same invention. Applicant, however, may serially prosecute up to two continuation applications that contain claims to the same invention as is claimed in a prior-filed divisional application if the continuation application satisfies the conditions of § 1.78(d)(1)(iii).

As discussed previously, applicants cannot rely upon a requirement for restriction including an election of species to file a divisional application in situations where: (1) The applicant traverses the requirement for restriction;

(2) the requirement for restriction may be conditional, such as a requirement for election of species in an application that contains a claim that is generic to all of the claimed species (see MPEP section 809); and (3) the claims to the non-elected invention may be rejoined at the request of the applicant (see MPEP § 821.04 *et seq.*). See the discussion of § 1.75(b)(5). This is because when the requirement for restriction is withdrawn in the prior-filed application, any divisional application that has been filed as the result of the restriction requirement of the prior-filed application will not be proper under §§ 1.78(a)(2) and 1.78(d)(1)(ii). Applicant is not permitted to file a divisional application of a prior-filed application that is no longer subject to a restriction requirement. Under §§ 1.78(a)(2) and 1.78(d)(1)(ii), the prior-filed application to which a divisional application claims the benefit must be subject to a requirement to comply with the requirement of unity of invention under PCT Rule 13 or a requirement for restriction under 35 U.S.C. 121. Sections 1.78(a)(2) and 1.78(d)(1)(ii) also require a divisional application to contain only claims directed to a non-elected invention that has not been examined.

For an application that contains a generic claim in which a requirement for an election of species has been made, applicants should conclude prosecution of the generic claim in the initial application and its continuation or continuation-in-part applications, including exhaustion of any available appeals, before even filing a divisional application to a non-elected species. If applicant no longer wants to pursue the generic claim, applicant may file a divisional application directed to a non-elected species. If applicant files a divisional application directed to a non-elected species, applicant must: (1) Cancel the claims to the non-elected species and the generic claim in the prior-filed application before a rejoinder or reinstatement occurs; (2) not present the non-elected claims and the generic claim in any continuation or continuation-in-part application of the initial application; and (3) not present the generic claim in the divisional application or any continuation application of the divisional application.

Under the Office's rejoinder practice, an applicant may request rejoinder of claims to a non-elected invention that depend from or otherwise require all the limitations of an allowable claim. See MPEP § 821.04 *et seq.* Applicants may retain claims to a non-elected invention in an application for possible rejoinder

in the event of the allowance of a claim to the elected invention. If applicant cancels all of the claims directed to a non-elected invention before rejoinder occurs and files a divisional application, the restriction requirement will not be withdrawn and the non-elected claims that are now canceled will not be rejoined. This will preserve applicant's rights under 35 U.S.C. 121 and § 1.78(d)(1)(ii). See MPEP § 821.04(b).

Section 1.78(d)(1)(iii) provides for continuation applications that claim the benefit of a divisional application (either directly or indirectly). Section 1.78(d)(1)(iii) permits such a continuation application of a prior-filed nonprovisional application or international application designating the United States of America if: (1) The application is a continuation application as defined in § 1.78(a)(3) that claims the benefit under 35 U.S.C. 120, 121, or 365(c) of a divisional application that satisfies the conditions set forth in § 1.78(d)(1)(ii); (2) the application discloses and claims only an invention or inventions that were disclosed and claimed in the divisional application; (3) the application claims the benefit of only the divisional application, any application to which such divisional application claims benefit under 35 U.S.C. 120, 121, or 365(c) in compliance with the conditions set forth in § 1.78(d)(1)(ii), and no more than one intervening prior-filed nonprovisional application (*i.e.*, only one continuation application of the divisional application filed between the divisional application and the second continuation application of the divisional application); and (4) no more than one other nonprovisional application claims the benefit of the divisional application. This does not include any other divisional application that satisfies the conditions set forth in § 1.78(d)(1)(ii) or any nonprovisional application that claims the benefit of such divisional application and satisfies the conditions set forth in § 1.78(d)(1)(iii) or (d)(1)(vi). Section 1.78(d)(1)(iii) permits an applicant to continue prosecution of a divisional application via two continuation applications (in parallel or serially). The Office, however, will treat each application prosecuted in parallel as having the total number of claims present in all of such applications for purposes of determining whether an examination support document is required by § 1.75(b) provided that the continuation application contains at least one claim that is patentably indistinct from at least one claim in the divisional application.

Section 1.78(d)(1)(iii) does not permit a continuation-in-part of a divisional application. Section 1.78(d)(1)(iii) is designed to permit an applicant to complete prosecution with respect to an invention or inventions that were disclosed and claimed in a divisional application, and not to permit an applicant to seek patent protection for a new invention that merely bears some relationship to an invention or inventions that were disclosed and claimed in a divisional application. Section 1.78(d)(1)(i) provides a mechanism for applicants to seek patent protection for a new invention that is an improvement of an invention or inventions that were disclosed and claimed in an initial or continuing (including a divisional) application.

The provisions of §§ 1.78(d)(1)(i) through (d)(1)(iii) are illustrated with the following example: (1) There is an initial application "A" that is subject to a restriction requirement under 35 U.S.C. 121 and § 1.141 *et seq.*; (2) a continuation application "B" of application "A"; (3) a further continuation application "C" which claims the benefit of continuation application "B" and initial application "A"; (4) a divisional application "D" (based upon the restriction requirement under 35 U.S.C. 121 and § 1.141 *et seq.* in application "A"), which claims the benefit of continuation application "C", continuation application "B", and initial application "A"; (5) a continuation application "E" of divisional application "D", which claims the benefit of divisional application "D", continuation application "C", continuation application "B", and initial application "A"; and (6) a further continuation application "F" of continuation application "E", which claims the benefit of continuation application "E", divisional application "D", continuation application "C", continuation application "B", and initial application "A".

Under § 1.78(d)(1)(i), application "C" is either a continuation application under § 1.78(a)(3) or a continuation-in-part application under § 1.78(a)(4) that claims the benefit of no more than two prior-filed applications "B" and "A". In addition, applications "B" and "A" whose benefit is claimed in application "C" have their benefit claimed in no more than one other application (not including divisional application "D" or continuation applications "E" and "F" of the divisional application "D"). That is, the benefit of application "A" is claimed in only one other application "B" (not including divisional application "D" or continuation

applications "E" and "F" of the divisional application "D"), and the benefit of application "B" is claimed in only one other application "C" (not including divisional application "D" or continuation applications "E" and "F" of the divisional application "D").

Under § 1.78(d)(1)(ii), nonprovisional application "D" is a divisional application under § 1.78(a)(2) since it claims the benefit of prior-filed application "A" that was subject to a requirement to comply with the requirement of unity of invention under PCT Rule 13 or a requirement for restriction under 35 U.S.C. 121. Divisional application "D" may contain only claims directed to an invention identified in the requirement to comply with the requirement of unity of invention or requirement for restriction but were not elected for examination in prior-filed application "A" or in any other nonprovisional application (applications "B" and "C"), except for a nonprovisional application (applications "E" and "F") that claims the benefit of divisional application "D" and satisfies the conditions of § 1.78(d)(1)(iii). That is, divisional application "D" may contain only claims directed to an invention or inventions that were identified in such requirement to comply with the requirement of unity of invention or requirement for restriction but were not elected for examination in any other application except for its continuation applications "E" and "F". Finally, the divisional application "D" claims the benefit of the prior-filed applications (applications "A", "B", and "C").

Under § 1.78(d)(1)(iii), nonprovisional application "F" is a continuation application under § 1.78(a)(3) that claims the benefit of divisional application "D". Application "D" is a divisional application that satisfies the conditions set forth in § 1.78(d)(1)(ii). The nonprovisional application "F" may disclose and claim only an invention that was disclosed and claimed in divisional application "D". The nonprovisional application "F" claims the benefit of only divisional application "D", the applications to which divisional application "D" claims benefit in compliance with the conditions of § 1.78(d)(1)(ii) (applications "A", "B", and "C"), and no more than one intervening prior-filed nonprovisional application (application "E"). Divisional application "D" whose benefit is claimed in nonprovisional application "E" and in nonprovisional application "F" has its benefit claimed in no more than one other nonprovisional application. That is, with respect to application "F",

divisional application "D" has its benefit claimed in no more than one other nonprovisional application (application "E"), and with respect to application "E", divisional application "D" has its benefit claimed in no more than one other nonprovisional application (application "F").

Section 1.78(d)(1)(iv) pertains to the situation in which an applicant files a bypass continuation (or continuation-in-part) application rather than paying the basic national fee (entering the national stage) in an international application in which a Demand for international preliminary examination (PCT Article 31) has not been filed, and the international application does not claim the benefit of any other nonprovisional application or international application designating the United States of America. Section 1.78(d)(1)(iv) provides that in this situation the applicant may file "one more" continuation application (or continuation-in-part application) without there being a requirement for a petition and showing under § 1.78(d)(1)(vi). A "bypass" continuation (or continuation-in-part) application is an application for patent filed under 35 U.S.C. 111(a) that claims the benefit of the filing date of an earlier international application designating the United States of America that did not enter the national stage under 35 U.S.C. 371. See H.R. Rep. No. 107-685, at 222 (2002).

Specifically, § 1.78(d)(1)(iv) provides that a continuation application or continuation-in-part application is permitted if the following conditions are met: (1) The application claims benefit under 35 U.S.C. 120 or 365(c) of a prior-filed international application designating the United States of America, and a Demand has not been filed and the basic national fee (§ 1.492(a)) has not been paid in the prior-filed international application and the prior-filed international application does not claim the benefit of any other nonprovisional application or international application designating the United States of America; (2) the application is a continuation application as defined in § 1.78(a)(3) or a continuation-in-part application as defined in § 1.78(a)(4) that claims the benefit under 35 U.S.C. 120, 121, or 365(c) of no more than three prior-filed applications; and (3) any application whose benefit is claimed under 35 U.S.C. 120, 121, or 365(c) in such nonprovisional application has its benefit claimed in no more than two other nonprovisional applications. This does not include any nonprovisional application that satisfies the conditions set forth in § 1.78(d)(1)(ii), (d)(1)(iii) or (d)(1)(vi).

Section 1.78(d)(1)(v) pertains to the situation in which an applicant files a continuation (or continuation-in-part) application to correct informalities rather than completing an application for examination under § 1.53 (*i.e.*, the prior-filed application became abandoned due to the failure to timely reply to an Office notice issued under § 1.53(f)). The prior-filed nonprovisional application, however, must be entitled to a filing date and have paid therein the basic filing fee within the pendency of the application. See § 1.78(d)(2). Section 1.78(d)(1)(v) provides that in this situation the applicant may file "one more" continuation application (or continuation-in-part application) without there being a requirement for a petition and showing under § 1.78(d)(1)(vi). Specifically, § 1.78(d)(1)(v) provides that a continuation application or continuation-in-part application is permitted if the following conditions are met: (1) The application claims benefit under 35 U.S.C. 120 or 365(c) of a prior-filed nonprovisional application filed under 35 U.S.C. 111(a), and the prior-filed nonprovisional application became abandoned due to the failure to timely reply to an Office notice issued under § 1.53(f) and does not claim the benefit of any other nonprovisional application or international application designating the United States of America; (2) the application is a continuation application as defined in § 1.78(a)(3) or a continuation-in-part application as defined in § 1.78(a)(4) that claims the benefit under 35 U.S.C. 120, 121, or 365(c) of no more than three prior-filed applications; and (3) any application whose benefit is claimed under 35 U.S.C. 120, 121, or 365(c) in such nonprovisional application has its benefit claimed in no more than two other nonprovisional applications. This does not include any nonprovisional application that satisfies the conditions set forth in § 1.78(d)(1)(ii), (d)(1)(iii) or (d)(1)(vi).

Section 1.78(d)(1)(vi) provides that a continuing nonprovisional application that is filed to obtain consideration of an amendment, argument, or evidence that could not have been submitted during the prosecution of the prior-filed application, and does not satisfy the conditions set forth in § 1.78(d)(1)(i), (ii), (iii), (iv) or (v), may claim the benefit under 35 U.S.C. 120, 121, or 365(c) of such prior-filed application. Under § 1.78(d)(1)(vi), a petition must be filed in such nonprovisional application that is accompanied by the fee set forth in § 1.17(f) and a showing

46734 Federal Register / Vol. 72, No. 161 / Tuesday, August 21, 2007 / Rules and Regulations

that the amendment, argument, or evidence sought to be entered could not have been submitted during the prosecution of the prior-filed application. This will permit an applicant to continue prosecution of an application via a continuing application to obtain consideration of an amendment, argument, or evidence that could not have been submitted during the prosecution of the prior-filed application. Section 1.78(d)(1)(vi) sets forth the time period within which such a petition must be provided: (1) if the later-filed continuing application is an application filed under 35 U.S.C. 111(a), within four months from the actual filing date of the later-filed application; and (2) if the continuing application is a nonprovisional application which entered the national stage from an international application after compliance with 35 U.S.C. 371, within four months from the date on which the national stage commenced under 35 U.S.C. 371(b) or (f) in the international application.

With respect to the application of the changes to § 1.78 in this final rule to a reissue application, benefit claims under 35 U.S.C. 120, 121, or 365(c) in the application for patent that is being reissued will not be taken into account in determining whether a continuing reissue application claiming the benefit under 35 U.S.C. 120, 121, or 365(c) of the reissue application satisfies one or more of the conditions set forth in §§ 1.78(d)(1)(i) through 1.78(d)(1)(vi). However, an applicant may not use the reissue process to add to the original patent benefit claims under 35 U.S.C. 120, 121, or 365(c) that do not satisfy one or more of the conditions set forth in §§ 1.78(d)(1)(i) through 1.78(d)(1)(vi), if the application for the original patent was filed on or after November 1, 2007.

Section 1.78(d)(2) provides that each prior-filed application must name as an inventor at least one inventor named in the later-filed application. In addition, each prior-filed application must either be: (1) An international application entitled to a filing date in accordance with PCT Article 11 and designating the United States of America; or (2) a nonprovisional application under 35 U.S.C. 111(a) that is entitled to a filing date as set forth in § 1.53(b) or § 1.53(d) for which the basic filing fee set forth in § 1.16 has been paid within the pendency of the application (provisions from former § 1.78(a)(1)).

Section 1.78(d)(3) is amended to include the parenthetical “(i.e., whether the later-filed application is a continuation, divisional, or continuation-in-part of the prior-filed nonprovisional application or

international application)” to clarify in the rules of practice what is meant by the requirement that an applicant identify the relationship of the applications. See MPEP § 201.11.

Section 1.78(d)(3) also provides that if an application is identified as a continuation-in-part application, the applicant must identify the claim or claims in the continuation-in-part application for which the subject matter is disclosed in the manner provided by 35 U.S.C. 112, ¶ 1, in the prior-filed application. Any claim in the continuation-in-part application for which the subject matter is not identified as being disclosed in the manner provided by 35 U.S.C. 112, ¶ 1, in the prior-filed application will be treated as entitled only to the actual filing date of the continuation-in-part application, and will be subject to prior art based on the actual filing date of the continuation-in-part application. As discussed previously, to avoid any unnecessary delay in the prosecution of the application, applicant should provide the identification before the examiner begins to conduct a prior art search. If the failure to identify the claims for which the subject matter is disclosed in the manner provided by 35 U.S.C. 112, ¶ 1, in the prior-filed application causes the examiner to include a new prior art rejection in a second or subsequent Office action, the inclusion of the new prior art rejection will not preclude the Office action from being made final.

This final rule eliminates from § 1.78(d) the provision that the prior-filed application disclose the invention claimed in at least one claim of the later-filed application in the manner provided by 35 U.S.C. 112, ¶ 1. For a later-filed application to receive the benefit of the filing date of a prior-filed application, 35 U.S.C. 120 requires that the prior-filed application must disclose the invention claimed in at least one claim of the later-filed application in the manner provided by 35 U.S.C. 112, ¶ 1. The Office, however, does not make a determination as to whether a prior-filed application discloses the invention claimed in a claim of the later-filed application in the manner provided by 35 U.S.C. 112, ¶ 1, unless that determination is necessary to determine the patentability of such claim. See MPEP § 201.08 (“Unless the filing date of the earlier nonprovisional application is actually needed * * *, there is no need for the Office to make a determination as to whether the requirement of 35 U.S.C. 120, that the earlier nonprovisional application discloses the invention of the second application in the manner provided by

35 U.S.C. 112, ¶ 1, is met and whether a substantial portion of all of the earlier nonprovisional application is repeated in the second application in a continuation-in-part situation. Accordingly, an alleged continuation-in-part application should be permitted to claim the benefit of the filing date of an earlier nonprovisional application if the alleged continuation-in-part application complies with the * * * formal requirements of 35 U.S.C. 120.”).

Section 1.78(d)(4) and (d)(5) contain the provisions of former § 1.78(a)(2).

Section 1.78(d)(6) provides that cross-references to applications for which a benefit is not claimed must be located in a paragraph separate from the paragraph containing the references to applications for which a benefit is claimed. Including cross-references to applications for which a benefit is not claimed in the same paragraph as the paragraph containing the references to applications for which a benefit is claimed may lead to the Office inadvertently scheduling the application for publication under 35 U.S.C. 122(b) and § 1.211 *et seq.* on the basis of the cross-referenced applications having the earliest filing date.

Section 1.78(e) contains provisions relating to delayed claims under 35 U.S.C. 120, 121, or 365(c) for benefit of prior-filed nonprovisional or international applications. Section 1.78(e) contains the provisions of former § 1.78(a)(3).

Section 1.78(f) contains provisions relating to applications and patents naming at least one inventor in common.

Section 1.78(f)(1)(i) provides that the applicant in a nonprovisional application that has not been allowed (§ 1.311) must identify by application number (i.e., series code and serial number) and patent number (if applicable) each other pending or patented nonprovisional application, in a separate paper, for which the following conditions are met: (1) The application has a filing date that is the same as or within two months of the filing date of the other pending or patented application, taking into account any filing date for which a benefit is sought under title 35, United States Code; (2) the application names at least one inventor in common with the other pending or patented application; and (3) the application is owned by the same person, or subject to an obligation of assignment to the same person, as the other pending or patented application. This identification requirement would also apply to each identified application because the identifying application has

a filing date that is the same as or within two months of the filing date of the identified application and vice versa.

The phrase "taking into account any filing date for which a benefit is sought under title 35, United States Code" in § 1.78(f)(1)(i)(A) means any filing date for which a benefit (or priority) is sought or claimed under 35 U.S.C. 111, 119, 120, 121, 363, or 365. Cf. 35 U.S.C. 122(b)(1)(A) (requires publication of patent applications "promptly after the expiration of a period of 18 months from the earliest filing date for which a benefit is sought under this title" (emphasis added), meaning eighteen months from the earliest filing date for which a benefit or priority is sought or claimed under 35 U.S.C. 111, 119, 120, 121, 363, or 365). Thus, if an application claims the benefit of or priority to other applications, "the filing date of [the application], taking into account any filing date for which a benefit is sought under title 35, United States Code," is the actual filing date of the application as well as the filing date of each application to which the application claims a benefit or priority. For example, if an application has a filing date of December 1, 2006, and claims the benefit of a nonprovisional application that was filed on June 1, 2004, and claims the priority of a foreign application that was filed on June 1, 2003, for purposes of §§ 1.78(f)(1) and (f)(2) the filing date of the application "taking into account any filing date for which a benefit is sought under title 35, United States Code," is December 1, 2006, June 1, 2004, and June 1, 2003.

The phrase "owned by the same person, or subject to an obligation of assignment to the same person" in § 1.78(f)(1)(i)(C) (and in § 1.78(f)(2)(i)(C) and 1.78(f)(3)) has the same meaning as it does in 35 U.S.C. 103(c). See MPEP § 706.02(l)(2) for a discussion of the definition of this phrase as it is used in 35 U.S.C. 103(c).

The phrase "has not been allowed" in § 1.78(f)(1)(i) (and in § 1.78(f)(2)(ii) and (iii)) means a notice of allowance under § 1.311 has not been mailed in the application, or a notice of allowance under § 1.311 has been mailed in the application but the application has been withdrawn from issue. Thus, the identification of such one or more other pending or patented nonprovisional applications under § 1.78(f)(1)(i) is not required in an application in which a notice of allowance has been mailed, unless the application is withdrawn from issue.

Section 1.78(f)(1)(ii) also provides that one or more other nonprovisional applications under § 1.78(f)(1)(i) must

be identified within the later of: (1) Four months from the actual filing date of a nonprovisional application filed under 35 U.S.C. 111(a); (2) four months from the date on which the national stage commenced under 35 U.S.C. 371(b) or (f) in a nonprovisional application entering the national stage from an international application under 35 U.S.C. 371; or (3) two months from the mailing date of the initial filing receipt in the other nonprovisional application that is required to be identified under § 1.78(f)(1)(i).

Section 1.78(f)(2)(i) provides that a rebuttable presumption shall exist that a nonprovisional application contains at least one claim that is not patentably distinct from at least one of the claims in the one or more other pending or patented nonprovisional applications if: (1) The application has a filing date that is the same as the filing date of another pending application or patent, taking into account any filing date for which a benefit is sought; (2) the application names at least one inventor in common with the other pending application or patent; (3) the application is owned by the same person, or subject to an obligation of assignment to the same person, as the other pending application or patent; and (4) the application contains substantially overlapping disclosure as the other pending application or patent. Section 1.78(f)(2)(i) further provides that substantial overlapping disclosure exists if the other pending or patented nonprovisional application has written description support under 35 U.S.C. 112, ¶ 1, for at least one claim in the nonprovisional application.

If these conditions exist, the applicant must under § 1.78(f)(2)(ii) in the nonprovisional application, unless the nonprovisional application has been allowed (§ 1.311), within the time period specified in § 1.78(f)(2)(iii) either: (1) Rebut this presumption by explaining how the application contains only claims that are patentably distinct from the claims in each of such other pending applications or patents; or (2) submit a terminal disclaimer in accordance with § 1.321(c). In addition, § 1.78(f)(2)(ii)(B) provides that where one or more other pending nonprovisional applications containing patentably indistinct claims have been identified, the applicant must explain why there are two or more pending nonprovisional applications naming at least one inventor in common and owned by the same person, or subject to an obligation of assignment to the same person, which contain patentably indistinct claims. Unless applicant presents good and sufficient reasons for

such multiple applications, the Office may require elimination of the patentably indistinct claims from all but one of the applications. See § 1.78(f)(3).

As discussed previously, for applications having a continuity relationship, the prior application must be pending at the time the continuing application is filed. See 35 U.S.C. 120 (requires that a continuing application be filed before the patenting or abandonment of or termination of proceedings on the prior application). An applicant is not required to provide an explanation under § 1.78(f)(2)(ii)(B) for a continuation application or continuation-in-part application of a prior-filed application that has been allowed, provided that the prior-filed application is not withdrawn from issue. Furthermore, where the other nonprovisional application containing patentably indistinct claims is allowed, the Office will not count the claims of the allowed application in determining whether the total number of claims present in all of the copending nonprovisional applications containing patentably indistinct claims exceeds the five independent claim and twenty-five total claim threshold under § 1.75(b)(4). See the discussion of § 1.75(b)(4). A terminal disclaimer in accordance with § 1.321(c) will, however, be required in each nonprovisional application containing patentably indistinct claims to overcome any obviousness-type double patenting rejection.

Under § 1.78(f)(2)(iii), the actions specified in § 1.78(f)(2)(ii) (if required) must be taken within the later of: (1) Four months from the actual filing date of a nonprovisional application filed under 35 U.S.C. 111(a); (2) four months from the date on which the national stage commenced under 35 U.S.C. 371(b) or (f) in a nonprovisional application entering the national stage from an international application under 35 U.S.C. 371; (3) the date on which a claim that is not patentably distinct from a claim in one or more other pending or patented applications is presented; or (4) two months from the mailing date of the initial filing receipt in the one or more other pending or patented applications.

The requirement under § 1.78(f)(2)(ii) for taking one of the actions specified in § 1.78(f)(2)(ii) does not apply to the applicant in the application in which a notice of allowance has been mailed, unless the application is withdrawn from issue (§ 1.313). For example, if an applicant filed a continuation application after a notice of allowance has been mailed in the prior-filed application, the applicant must either rebut the presumption under

§ 1.78(f)(2)(i) or submit a terminal disclaimer in accordance with § 1.321(c) within the time period set forth in § 1.78(f)(2)(iii) in the continuation application. Under § 1.78(f)(2)(ii), the applicant, however, is not required to rebut the presumption or submit a terminal disclaimer in the allowed prior-filed application. Nevertheless, a terminal disclaimer in accordance with § 1.321(c) will be required in each nonprovisional application containing patentably indistinct claims to overcome any obviousness-type double patenting rejection.

As discussed previously, when an applicant files multiple applications that are substantially the same, the applicant is responsible for assisting the Office in resolving potential double patenting situations, rather than taking no action until faced with a double patenting rejection. Thus, if an Office action must include a double patenting rejection (either statutory or obviousness-type double patenting), it is because the applicant has not met his or her responsibility to resolve the double patenting situation. Therefore, the inclusion of a new double patenting rejection in a second or subsequent Office action will not preclude the Office action from being made final.

Section 1.78(f)(3) applies when there are two or more commonly owned (owned by the same person, or are subject to an obligation of assignment to the same person) nonprovisional applications containing patentably indistinct claims. Under § 1.78(f)(3), unless applicant presents good and sufficient reasons for such multiple applications, the Office may require elimination of the patentably indistinct claims from all but one of the applications. Section 1.78(f)(3) contains provisions similar to former § 1.78(b). The Office expects to apply this provision primarily in situations covered by § 1.78(f)(2)(ii), under which applicants must explain why it is necessary that there are two or more pending nonprovisional applications naming at least one inventor in common and owned by the same person, or subject to an obligation of assignment to the same person, which contain patentably indistinct claims. The Office, however, may require that an applicant provide good and sufficient reason whenever there are two or more pending nonprovisional applications with such common ownership or assignment obligation and patentably indistinct claims, regardless of the relative filing dates of the applications. Section 1.78(f)(3) does not apply to the claims in a patent.

The following are two examples where an applicant may have a good and sufficient reason under § 1.78(f)(3) for there being two or more pending nonprovisional applications that contain patentably indistinct claims: (1) An applicant filed a continuation application after the mailing of a notice of allowance in the prior-filed application, but the allowance of the prior-filed application was subsequently withdrawn by the Office; or (2) an interference was declared in an application that contains both claims corresponding to the count and claims not corresponding to the count, the BPAI suggests that the claims not corresponding to the count be canceled from the application in interference and pursued in a separate application, and the applicant filed a continuation application to present the claims not corresponding to the count. These examples are merely illustrative and not exhaustive.

Section 1.78(g) addresses applications or patents under reexamination that name different inventors and contain patentably indistinct claims. Section 1.78(g) contains the provisions of former § 1.78(c), except that "conflicting claims" is changed to "patentably indistinct claims" for clarity and for consistency with the language of § 1.78(f).

Section 1.78(h) covers the situation in which parties to a joint research agreement are treated (in essence) as a common owner for purposes of 35 U.S.C. 103 by virtue of the CREATE Act. Section 1.78(h) provides that if an application discloses or is amended to disclose the names of parties to a joint research agreement under 35 U.S.C. 103(c)(2)(C), the parties to the joint research agreement are considered to be the same person for purposes of § 1.78. The CREATE Act amended 35 U.S.C. 103(c) to provide that subject matter developed under a joint research agreement shall be treated as owned by the same person or subject to an obligation of assignment to the same person for purposes of determining obviousness if three conditions are met: (1) The claimed invention was made by or on behalf of parties to a joint research agreement that was in effect on or before the date the claimed invention was made; (2) the claimed invention was made as a result of activities undertaken within the scope of the joint research agreement; and (3) the application for patent for the claimed invention discloses or is amended to disclose the names of the parties to the joint research agreement. See *Changes to Implement the Cooperative Research and Technology Enhancement Act of 2004*,

70 FR 1818, 1818 (Jan. 11, 2005), 1291 *Off. Gaz. Pat. Office* 58, 58–59 (Feb. 8, 2005) (final rule). Section 1.78(h) also provides that if the application is amended to disclose the names of parties to a joint research agreement, the applicant must identify the one or more other nonprovisional applications as required by § 1.78(f)(1) with the amendment unless the applications have been identified within the four-month period specified in § 1.78(f)(1).

Section 1.78(i) provides that the time periods set forth in § 1.78 are not extendable.

The changes to § 1.78 (except §§ 1.78(a) and 1.78(d)(1)) are applicable to any nonprovisional application pending on or after November 1, 2007. The changes to §§ 1.78(a) and 1.78(d)(1) are applicable to any application filed on or after November 1, 2007, or any application entering the national stage after compliance with 35 U.S.C. 371 on or after November 1, 2007. Except as otherwise indicated in this final rule, any application filed under 35 U.S.C. 111(a) on or after November 1, 2007, or any application entering the national stage after compliance with 35 U.S.C. 371 on or after November 1, 2007, seeking to claim the benefit under 35 U.S.C. 120, 121, or 365(c) and § 1.78 of a prior-filed nonprovisional application or international application must either: (1) Meet the requirements specified in one of §§ 1.78(d)(1)(i) through (d)(1)(v); or (2) include a grantable petition under § 1.78(d)(1)(vi).

With respect to applications that claim the benefit under 35 U.S.C. 120, 121, or 365(c) only of nonprovisional applications or international applications filed before August 21, 2007: An application is not required to meet the requirements set forth in § 1.78(d)(1) if: (1) The application claims the benefit under 35 U.S.C. 120, 121, or 365(c) only of prior-filed nonprovisional applications filed before August 21, 2007 or prior-filed applications entering the national stage after compliance with 35 U.S.C. 371 before August 21, 2007; and (2) there is no other application filed on or after the publication date of this final rule in the *Federal Register* that also claims the benefit under 35 U.S.C. 120, 121, or 365(c) of such prior-filed nonprovisional applications or international applications. This provision will provide applicants with "one more" continuation application or continuation-in-part application of a second or subsequent continuing application (continuation application or continuation-in-part application) that was filed prior to the publication date of this final rule in the *Federal Register*.

without a petition under § 1.78(d)(1)(vi). Thus, an applicant may file a single continuation application or continuation-in-part application on or after November 1, 2007, without meeting the requirements specified in § 1.78(d)(1)(i) through (d)(1)(v), or including a petition under § 1.78(d)(1)(vi), even if the prior-filed application was a second or subsequent continuation or continuation-in-part application. It should be noted that the purpose of this provision is to ensure that an applicant may file "one more" continuation application or continuation-in-part application of an application that was filed prior to the publication date of this final rule in the *Federal Register* without a petition and showing, and not to provide an "extra" continuation application or continuation-in-part application for applications filed prior to the publication date of this final rule in the *Federal Register*. If an application filed before the publication date of this final rule in the *Federal Register* is not a continuing application or is only the first continuing application, this provision will not entitle an applicant to file a third or subsequent continuation or continuation-in-part application without a petition under § 1.78(d)(1)(vi) showing that the amendment, argument, or evidence sought to be entered could not have been submitted during the prosecution of the prior-filed application.

Section 1.104 (nature of examination): The Office proposed a number of changes to § 1.104 to implement the "representative claims" examination approach. See *Changes to Practice for the Examination of Claims in Patent Applications*, 71 FR at 64, 68, 1302 Off. Gaz. Pat. Office at 1131, 1332. The Office is not proceeding with the changes to § 1.104 to implement the "representative claims" examination approach, but is revising § 1.104 for consistency with current examination practices.

Section 1.104(a)(1) is amended to add the phrase "and other requirements" to the phrase "the examination shall be complete with respect both to compliance of the application or patent under reexamination with the applicable statutes and rules" to address situations in which the requirement is based upon Office practice as set forth in the MPEP or in the case law. For example, the phrase "other requirements" would address the situation in which a claim did not comply with the requirement in MPEP § 608.01(m) that each claim be the object of a single sentence starting with "I (or we) claim," "The invention claimed is,"

or the equivalent. See *Fressola v. Manbeck*, 36 U.S.P.Q.2d 1211, 1212 (D.C. 1995). In addition, in the event that there is a requirement for restriction including election of species, or both, the provision in § 1.104(a)(1) for a "thorough study [and] investigation of the available prior art relating to the subject matter of the claimed invention" will continue to apply only with respect to the invention and species elected for examination on the merits. This provision of § 1.104 does not apply with respect to an invention or species that has been withdrawn from consideration as a result of a requirement for restriction, including an election of species.

Section 1.104(b) is also amended to delete the sentence "[h]owever, matters of form need not be raised by the examiner until a claim is found allowable." The Office would prefer that all matters of form be resolved at the earliest time during the patent examination process. Nevertheless, an Office action would not be considered improper simply because the Office action did not raise every applicable issue of form present in the application.

Section 1.105 (requirements for information): Section 1.105(a)(1) is amended to provide that an applicant may be required to set forth where (by page and line or paragraph number) in the specification of the application, or any application the benefit of whose filing date is sought under title 35, United States Code, there is written description support for the invention as defined in the claims (whether in independent or dependent form), and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the invention, under 35 U.S.C. 112, ¶ 1. Therefore, in situations in which it is not readily apparent where the specification of the application, or an application for which a benefit is claimed, provides written description support and enablement under 35 U.S.C. 112, ¶ 1, for a claim or a limitation of a claim, the examiner may require the applicant to provide such information. The Office considers this authority to be inherent under the patent statute and existing rules (including § 1.105), but is revising § 1.105 to make the authority explicit.

Section 1.110 (inventorship and date of invention of the subject matter of individual claims): Section 1.110 is amended to refer to § 1.78, rather than a specific paragraph (paragraph (c)) of § 1.78. The first sentence of § 1.110 is also amended to relocate the phrase

"when necessary for purposes of an Office proceeding" to the end of the sentence for clarity.

Section 1.114 (request for continued examination): Under § 1.114, an applicant is permitted to file a single request for continued examination without a petition and showing in a single application family. See § 1.114(f)(1). An application family includes the initial application and its continuation or continuation-in-part applications. An applicant is also permitted to file a single request for continued examination without a petition and showing in a divisional application family. See §§ 1.114(f)(2) and (f)(3). A divisional application family includes the divisional application and its continuation applications. An applicant may file a second or subsequent request for continued examination if the applicant files a petition and a showing that the amendment, argument, or evidence sought to be entered could not have been submitted earlier. See § 1.114(g).

Section 1.114(a) is amended to make clear that an applicant may not file an unrestricted number of requests for continued examination, that a request for continued examination must include a petition under § 1.114(g) unless the conditions set forth in § 1.114(f)(1), (f)(2), or (f)(3) are satisfied, and that a request for continued examination must be identified as a request for continued examination. Section 1.114(a) otherwise contains the provisions of former § 1.114(a).

Section 1.114(d) is revised to eliminate the sentence "[i]f an applicant timely files a submission and fee set forth in § 1.17(e), the Office will withdraw the finality of any Office action and the submission will be entered and considered." This change is to avoid misleading applicants into believing that the Office will *pro forma* withdraw the finality of any Office action and the submission will be *pro forma* entered and considered upon timely filing of a submission and fee set forth in § 1.17(e). Under revised § 1.114, a second or subsequent request for continued examination must also include a petition accompanied by the fee set forth in § 1.17(f) except under the conditions set forth in § 1.114(f).

Section 1.114(f) provides the conditions under which an applicant may file a request for continued examination under § 1.114 without a petition under § 1.114(g).

Section 1.114(f)(1) permits an applicant to file a single request for continued examination in any one (but only one) of an initial application or its continuation applications or

46738 Federal Register/Vol. 72, No. 161/Tuesday, August 21, 2007/Rules and Regulations

continuation-in-part applications. Section 1.114(f)(1) provides that an applicant may file a request for continued examination under § 1.114 without a petition under § 1.114(g) if a request for continued examination has not been previously filed in any of: (1) The application; (2) any application whose benefit is claimed in the application under 35 U.S.C. 120, 121, or 365(c); and (3) any application that claims the benefit under 35 U.S.C. 120, 121, or 365(c) of the application, not including any nonprovisional application that satisfies the conditions set forth in § 1.78(d)(1)(ii), 1.78(d)(1)(iii) or 1.78(d)(1)(vi). For example, if applicant filed one request for continued examination in an initial application, applicant is precluded from filing a second request for continued examination in the initial application and in any continuation applications or continuation-in-part applications that claim the benefit of the initial application (not including any nonprovisional application that satisfies the conditions set forth in § 1.78(d)(1)(ii), 1.78(d)(1)(iii) or 1.78(d)(1)(vi)), without a petition under § 1.114(g).

Section 1.114(f)(2) permits an applicant to file a single request for continued examination under § 1.114 in a divisional application meeting the conditions set forth in § 1.78(d)(1)(ii) provided that no request for continued examination has been filed in any continuation application of the divisional application. Section 1.114(f)(2) provides that an applicant may file request for continued examination under § 1.114 in a divisional application without a petition under § 1.114(g) if a request for continued examination has not previously been filed in any of: (1) The divisional application; and (2) any application that claims the benefit under 35 U.S.C. 120, 121, or 365(c) of that divisional application, not including any nonprovisional application that satisfies the conditions set forth in § 1.78(d)(1)(ii), (d)(1)(iii) or (d)(1)(vi).

Section 1.114(f)(3) permits an applicant to file a single request for continued examination in a continuation application of a divisional application meeting the conditions set forth in § 1.78(d)(1)(ii) provided that no request for continued examination has been filed in the divisional application or any other continuation application of the divisional application. Section 1.114(f)(3) provides that an applicant may file a request for continued examination under § 1.114 in a continuation application of a divisional

application without a petition under § 1.114(g) if a request for continued examination has not previously been filed in any of: (1) The continuation application; (2) the divisional application; and (3) any other application that claims the benefit under 35 U.S.C. 120, 121, or 365(c) of that divisional application, not including any nonprovisional application that satisfies the conditions set forth in § 1.78(d)(1)(ii), (d)(1)(iii) or (d)(1)(vi).

The provisions of § 1.114(f) are illustrated with the following example (the example used to illustrate the provisions of §§ 1.78(d)(1)(i) through (d)(1)(iii)): (1) There is an initial application "A" that is subject to a restriction requirement under 35 U.S.C. 121 and § 1.141 *et seq.*; (2) a continuation application "B" of application "A"; (3) a further continuation application "C" which claims the benefit of continuation application "B" and initial application "A"; (4) a divisional application "D" (based upon the restriction requirement under 35 U.S.C. 121 and § 1.141 *et seq.* in application "A"), which claims the benefit of continuation application "C", continuation application "B", and initial application "A"; (5) a continuation application "E" of divisional application "D", which claims the benefit of divisional application "D", continuation application "C", continuation application "B", and initial application "A"; and (6) a further continuation application "F" of continuation application "E", which claims the benefit of continuation application "E", divisional application "D", continuation application "C", continuation application "B", and initial application "A".

Section 1.114(f)(1) permits the filing of a single request for continued examination without a petition under § 1.114(g) in any one of applications "A", "B", or "C". Specifically, a request for continued examination may be filed in application "A", if a request for continued examination has not previously been filed in any of: (1) application "A"; (2) any application (none) whose benefit is claimed in application "A"; and (3) any application (applications "B" and "C") that claims the benefit of application "A", not including divisional application "D" and its continuation applications "E" and "F". In addition, a request for continued examination may be filed in application "B", if a request for continued examination has not previously been filed in any of: (1) Application "B"; (2) any application

(application "A") whose benefit is claimed in application "B"; and (3) any application (application "C") that claims the benefit of application "B", not including divisional application "D" and its continuation applications "E" and "F". Finally, a request for continued examination may be filed in application "C", if a request for continued examination has not previously been filed in any of: (1) Application "C"; (2) any application (applications "A" and "B") whose benefit is claimed in application "C"; and (3) any application (none) that claims the benefit of application "C", not including divisional application "D" and its continuation applications "E" and "F".

Section 1.114(f)(2) permits the filing of a single request for continued examination without a petition under § 1.114(g) in application "D", if a request for continued examination has not previously been filed in application "E" or application "F". Specifically, a request for continued examination may be filed in application "D", if a request for continued examination has not previously been filed in any of: (1) Divisional application "D"; and (2) any application (applications "E" and "F") that claims the benefit of divisional application "D".

Section 1.114(f)(3) permits the filing of a single request for continued examination without a petition under § 1.114(g) in any one of applications "E" or "F", if a request for continued examination has not previously been filed in application "D". Specifically, a request for continued examination may be filed in continuation application "E", if a request for continued examination has not previously been filed in any of: (1) Continuation application "E"; (2) divisional application "D"; and (3) any other application (application "F") that claims the benefit of divisional application "D". In addition, a request for continued examination may be filed in continuation application "F", if a request for continued examination has not previously been filed in any of: (1) continuation application "F"; (2) divisional application "D"; and (3) any other application (application "E") that claims the benefit of divisional application "D".

Section 1.114(g) provides that a request for continued examination must include a petition accompanied by the fee set forth in § 1.17(f) and a showing that the amendment, argument, or evidence sought to be entered could not have been submitted before the close of prosecution in the application. A petition under § 1.114(g) and the fee set forth in § 1.17(f) are not required if the

conditions set forth in § 1.114(f) are satisfied. Since a petition under § 1.114(g) requires a showing that there is an amendment, argument, or evidence that could not have been submitted prior to the close of prosecution in the application, a petition under § 1.114(g) for a request for continued examination including only an information disclosure statement as the submission required by § 1.114(c) (*i.e.*, not including an amendment, argument, or evidence) would not be granted.

Thus, an applicant may file a single request for continued examination without a petition under § 1.114(g) in any one (but only one) of an initial application or its continuation applications or continuation-in-part applications. An applicant may also file a single request for continued examination without a petition under § 1.114(g) in any one (but only one) of a divisional application (meeting the conditions set forth in § 1.78(d)(1)(ii)) or its continuation applications. Any second or subsequent request for continued examination in an application or application family must include a petition, accompanied by the fee set forth in § 1.17(f), and a showing that the amendment, argument, or evidence sought to be entered could not have been submitted prior to the close of prosecution in the application.

Section 1.114(h) provides that the filing of an improper request for continued examination, including a request for continued examination with a petition under § 1.114(g) that is not grantable, will not stay any period for reply or other proceedings. This is consistent with the current practice for requests for continued examination. See MPEP § 706.07(h), subsection V (the mere request for continued examination and fee will not operate to toll the running of any time period set in the previous Office action for reply to avoid abandonment of the application).

The Office proposed § 1.114(f) to include: “[a]ny other proffer of a request for continued examination in an application not on appeal will be treated as a submission under § 1.116. Any other proffer of a request for continued examination in an application on appeal will be treated only as a request to withdraw the appeal.” See *Changes to Practice for Continuing Applications, Requests for Continued Examination Practice, and Applications Containing Potentially Indistinct Claims*, 71 FR at 61, 1302 Off. Gaz. Pat. Office 1329. This final rule does not adopt that proposed change because it is unnecessary. Section 1.116 applies only to amendments, affidavits, and other evidence filed after the mailing of a final

Office action but prior to an appeal. However, applicants are permitted to file a request for continued examination under § 1.114 after the mailing of a notice of allowance or an action that otherwise closes prosecution in the application (e.g., an Office action under *Ex parte Quayle*, 1935 Dec. Comm'r Pat. 11 (1935)). See § 1.114(b). Furthermore, § 1.114(d) already provides for the situation in which a request for continued examination is filed in an application on appeal.

As discussed previously, applicants are permitted to file two continuation or continuation-in-part applications and a single request for continued examination without any justification. The provisions of § 1.78(d)(1) are independent of the provisions of § 1.114. Thus, filing a request for continued examination does not preclude an applicant from filing a first or second continuation application (or continuation-in-part application). In addition, an applicant may not agree to forgo a first or second continuation application (or continuation-in-part application) to obtain a second or third request for continued examination, nor can applicant forgo a request for continued examination to obtain a third continuation or continuation-in-part application. For example, an applicant cannot file two requests for continued examination without a petition and showing in an application instead of filing one of the two permitted continuation applications.

The Office is implementing an optional streamlined continuation application procedure under which an applicant may have a continuation application placed on an examiner's amended (Regular Amended) docket (see discussion of § 1.78(d)(1)(i)). Thus, an applicant may effectively obtain the docketing benefit (*i.e.*, being placed on an examiner's amended (Regular Amended) docket) of a second and third request for continued examination without a petition under § 1.114(g) by requesting that the two continuation applications permitted under § 1.78(d)(1)(i) be treated under the optional streamlined continuation application procedure.

The changes to § 1.114 apply to any application in which a request for continued examination is filed on or after November 1, 2007. Thus, a request for continued examination filed on or after November 1, 2007, in an application in which a request for continued examination has previously been filed, in a continuation or continuation-in-part application of an application in which a request for continued examination has previously

been filed, or in an application whose benefit is claimed in any other nonprovisional application in which a request for continued examination has previously been filed, must include a petition under § 1.114(g). That is, an applicant may file a request for continued examination (and not “one more” request for continued examination) on or after November 1, 2007, without a petition under § 1.114(g) only if the conditions set forth in § 1.114(f)(1), (f)(2), or (f)(3) are met.

Section 1.117 (refund due to cancellation of claim): The Consolidated Appropriations Act provides that 35 U.S.C. 41(a), (b), and (d) shall be administered in a manner that revises patent application fees (35 U.S.C. 41(a)) and patent maintenance fees (35 U.S.C. 41(b)), and provides for a separate filing fee (35 U.S.C. 41(a)), search fee (35 U.S.C. 41(d)(1)), and examination fee (35 U.S.C. 41(a)(3)) during fiscal years 2005 and 2006. See Public Law 108-447, 118 Stat. 2809 (2004). The Consolidated Appropriations Act also provides that the Office may, by regulation, provide for a refund of any part of the excess claim fee specified in 35 U.S.C. 41(a)(2) for any claim that is canceled before an examination on the merits has been made of the application under 35 U.S.C. 131. See 35 U.S.C. 41(a)(2) (as administered during fiscal years 2005 and 2006 pursuant to the Consolidated Appropriations Act). The Revised Continuing Appropriations Resolution, 2007 (Pub. L. 110-5, 121 Stat. 8 (2007)), keeps the patent fee and fee structure provisions of the Consolidated Appropriations Act, 2005, in effect during fiscal year 2007 (until September 30, 2007).

Section 1.117 is added to implement this provision of the Consolidated Appropriations Act. Section 1.117(a) provides that if an amendment canceling a claim is filed before an examination on the merits has been made of the application, the applicant may request a refund of any fee under § 1.16(h), (i), or (j) or under § 1.492(d), (e), or (f) paid on or after December 8, 2004, for such claim. Thus, if an applicant decides to cancel the claims in excess of five independent claims and in excess of twenty-five total claims rather than provide an examination support document in compliance with § 1.265, the applicant may request a refund of any fee for such claim that is paid on or after December 8, 2004. Section 1.117(a) as adopted, however, does not require that the amendment have been filed in reply to a notice under § 1.75(b)(3). Section 1.117(a) requires only that the amendment have been filed before an examination on the

46740 Federal Register/Vol. 72, No. 161/Tuesday, August 21, 2007/Rules and Regulations

merits has been made of the application. The Consolidated Appropriations Act authorizes a refund only for a claim that has been canceled before an examination on the merits has been made of the application under 35 U.S.C. 131. The Office thus lacks authority to grant a refund either on the basis of: (1) The withdrawal from consideration of a claim directed to a non-elected invention or species; or (2) the cancellation of a claim after an examination on the merits has been made of the application under 35 U.S.C. 131. Section 1.117(a) also provides that if an amendment adding one or more claims is also filed before the application has been taken up for examination on the merits, the Office may apply any refund under § 1.117 to any excess claims fees due as a result of such an amendment. The date indicated on any certificate of mailing or transmission under § 1.8 will not be taken into account in determining whether an amendment canceling a claim was filed before an examination on the merits has been made of the application.

* "[A]n examination on the merits has been made of the application" for purposes of § 1.117(a) once a first Office action on the merits, notice of allowability or allowance, or action under *Ex parte Quayle* is shown in the Patent Application Locating and Monitoring (PALM) system as having been counted. For purposes of § 1.117(a), "before" means at least one day before. If an amendment canceling a claim is filed and an Office action is counted on the same day, the amendment canceling a claim was not filed before an examination on the merits has been made of the application. The Patent Application Information Retrieval (PAIR) system is a system that provides public access to PALM for patents and applications that have been published. The PAIR system does not provide public access to information concerning applications that are maintained in confidence under 35 U.S.C. 122(a). Applicants, however, may use the private side of PAIR to access confidential information about their pending application. To access the private side of PAIR, a customer number must be associated with the correspondence address for the application, and the user of the system must have a digital certificate. For further information, contact the Customer Support Center of the Electronic Business Center at (571) 272-4100 or toll free at (866) 217-9197.

Section 1.117(b) (§ 1.117(c) as proposed) provides that if a request for refund under this section is not filed

within two months from the date on which the claim was canceled, the Office may retain the excess claims fee paid in the application. This two-month period is not extendable. If an amendment canceling a claim is not filed before an examination on the merits, the Office will not refund any part of the excess claims fee paid in the application except as provided in § 1.26.

The provisions of § 1.117(b) as proposed are duplicative of the provisions of § 1.138(d) and have not been adopted as unnecessary.

The patent fee provisions of the Consolidated Appropriations Act expire (in the absence of additional legislation) on September 30, 2007 (at the end of fiscal year 2007). Therefore, in the absence of subsequent legislation, the refund provision in § 1.117 will likewise expire on September 30, 2007 (at the end of fiscal year 2007), regardless of the date on which the excess claims fee was paid.

Section 1.136 (extensions of time): Section 1.136(a)(1) is amended to add "[t]he reply is to a notice requiring compliance with § 1.75(b) or § 1.265" to the enumerated list of replies to which the extension of time provision of § 1.136(a) is not applicable. A notice under § 1.75(b)(3) is a "notice requiring compliance with § 1.75(b)." A "notice requiring compliance with § 1.75(b)" would include a notice mailed before the issuance of a first Office action on the merits setting a two-month time period within which the applicant must: (1) File an examination support document in compliance with § 1.265; or (2) amend the application such that it contains no more than five independent claims and no more than twenty-five total claims. A "notice requiring compliance with § 1.75(b)" would also include a notice issued after a first Office action on the merits in an application in which the applicant is given a time period within which the applicant must amend the application such that it contains no more than five independent claims and no more than twenty-five total claims. For example, if a reply to a non-final Office action on the merits seeks to amend an application such that it contains more than five independent claims and more than twenty-five total claims, the reply would be held non-responsive and (if the non-compliance with § 1.75(b) appears to have been inadvertent) the Office would give the applicant a two-month time period that was not extendable under § 1.136(a) within which to provide an amendment that does not result in the application containing more than five independent

claims or more than twenty-five total claims. See § 1.135(c).

Section 1.142 (requirement for restriction): Section 1.142(a) is amended to state that an examiner "may" (rather than "will") require restriction if two or more independent and distinct inventions are claimed in a single application. The change is for consistency with current Office practice under which a requirement that an application containing claims to two or more independent and distinct inventions be restricted to a single invention is discretionary (see 35 U.S.C. 121 and MPEP § 803.01). An application containing claims to two or more independent and distinct inventions typically is not restricted to a single invention if the search and examination of all of the claims in the application can be made without serious burden (see MPEP section 803).

Section 1.142(c) is added to permit applicants to suggest requirements for restriction. Specifically, § 1.142(c) provides that if two or more independent and distinct inventions are claimed in a single application, the applicant may file a suggested requirement for restriction under § 1.142(c). Any suggested requirement for restriction must be filed before the earlier of the first Office action on the merits or an Office action that contains a requirement to comply with the requirement of unity of invention under PCT Rule 13 or a requirement for restriction under 35 U.S.C. 121 in the application. It must also be accompanied by an election without traverse of an invention to which there are no more than five independent claims and no more than twenty-five total claims, and must identify the claims to the elected invention. Claims to the non-elected invention, if not canceled, will be withdrawn from further consideration by the examiner. If the examiner accepts the suggested restriction, then the claims to the non-elected invention, if not canceled by the applicant, will be withdrawn from further consideration by the examiner. See the discussion of §§ 1.75(b)(5) and 1.78(d)(1)(ii).

Section 1.75(b)(3)(iii) as proposed would have permitted applicants to reply to a notice from the Office that an application contains more than ten representative claims (under certain conditions) by submitting a suggested requirement for restriction accompanied by an election without traverse of an invention to which there are no more than five independent claims and no more than twenty-five total claims. See *Changes to Practice for the Examination of Claims in Patent Applications*, 71 FR

at 64, 67–68, 1302 *Off. Gaz. Pat. Office* 1331, 1334. However, because the "representative claims" examination approach is not adopted in this final rule, this proposed provision of § 1.75(b)(3)(iii) is unnecessary. In this final rule, applicants may file a suggested requirement for restriction accompanied by an election without traverse (§ 1.142(c)) of an invention to which there are no more than five independent claims and no more than twenty-five total claims without first awaiting a notice from the Office under § 1.75(b)(3).

Section 1.142(c) further provides that if the applicant's suggested requirement for restriction is accepted, the restriction requirement will be set forth in a subsequent Office action. Any claim to the non-elected invention or inventions, if not canceled, is by the election withdrawn from further consideration.

If the suggested requirement for restriction is refused, the applicant will be notified in an Office action. That Office action may include, a notice under § 1.75(b)(3) requiring applicant to file an examination support document or amend the application to contain no more than five independent claims or no more than twenty-five total claims. If an applicant's suggested restriction requirement is refused, the examiner may make a different restriction requirement or make no restriction requirement. 35 U.S.C. 121 authorizes, but does not compel, the Director to require that an application containing two or more independent and distinct inventions be restricted to one of the inventions. A decision not to restrict an application to a single invention is not an action or requirement within the meaning of § 1.181(a). Thus, any review of an examiner's requirement for restriction that differs from a suggested restriction requirement will only concern the appropriateness of the examiner's restriction requirement and will not address the appropriateness of the applicant's suggested restriction requirement or compare the examiner's restriction requirement and the suggested restriction requirement.

Section 1.145 (subsequent presentation of claims for different invention): Section 1.145 is amended to state that an applicant "may" (rather than "will") be required to restrict the claims to the invention previously claimed if, after an Office action on an application, the applicant presents claims directed to an invention distinct from and independent of the invention previously claimed (see discussion of § 1.142(a)). Section 1.145 is amended to add "on the merits" to clarify that

§ 1.145 applies only after a first Office action on the merits.

Section 1.265 (examination support document): Section 1.265 is added to set forth what an "examination support document" entails. An examination support document is required under § 1.75(b)(1) when an applicant presents more than five independent claims or more than twenty-five total claims in an application. See § 1.75(b)(1) and the discussion of § 1.75(b)(1). Section 1.265(a) sets forth the requirements for an examination support document. Section 1.265(b) provides for the requirements of the preexamination search required under § 1.265(a)(1). Section 1.265(c) provides for the requirements of the listing of references required under § 1.265(a)(2). Section 1.265(d) provides for certain situations in which a supplemental examination support document is required when applicant files an information disclosure statement citing additional references. Section 1.265(e) provides for situations in which the examination support document is insufficient. Section 1.265(f) provides an exemption to applications filed by a small entity as defined by the Regulatory Flexibility Act (5 U.S.C. 601 et seq.). The exemption is for the requirement in § 1.265(a)(3) that an examination support document must include an identification of all of the claim limitations (whether in independent or dependent form) that are disclosed by the cited references.

Section 1.265 contains fewer requirements than an accelerated examination support document under the revised procedures for certain petitions to make special (see *Changes to Practice for Petitions in Patent Applications To Make Special and for Accelerated Examination*, 71 FR 36232 (June 26, 2006), 1308 *Off. Gaz. Pat. Office* 106 (July 18, 2006) (notice)). For example, § 1.265 does not require that the examination support document identify any cited references that may be disqualified as prior art under 35 U.S.C. 103(c) as amended by the Cooperative Research and Technology Act (although applicants are encouraged to identify any cited references that may be so disqualified). Thus, the Office's guidelines concerning the accelerated examination support document may be helpful to applicants who are preparing an examination support document under § 1.265. The guidelines under the revised accelerated examination procedure, search templates, and samples of a preexamination search document and an examination support document can be found on the Office's Internet Web site at <http://www.uspto.gov/web/patents/accelerated/>.

The Office will provide similar guidelines for examination support document under § 1.265 and will post such guidelines on the Office's Internet Web site.

Section 1.265(a)(1) provides that an examination support document must include a statement that a preexamination search in compliance with § 1.265(b) was conducted. The examination support document must identify (in the manner set forth in MPEP § 719.05) the field of search by class and subclass and the date of the search, where applicable. For database searches, the examination support document must identify the search logic or chemical structure or sequence used as a query, the name of the file or files searched and the database service, and the date of the search.

Section 1.265(a)(2) provides that an examination support document must include a listing in compliance with § 1.265(c) of the reference or references deemed most closely related to the subject matter of each of the claims (whether in independent or dependent form). The references that would be most closely related to the subject matter of each of the claims include: (1) A reference that discloses the most number of limitations in an independent claim; (2) a reference that discloses a limitation of an independent claim that is not shown in any other reference in the listing of references required under § 1.265(a)(2); and (3) a reference that discloses a limitation of a dependent claim that is not shown in any other reference in the listing of references required under § 1.265(a)(2). References that are only relevant to the general subject matter of the claims would not be most closely related to the subject matter of each of the claims if there are other references that are deemed to be more closely related to the subject matter of the claims.

It is envisioned that the reference or references presented as being most closely related to the subject matter of the claims will generally be references that result from the preexamination search provided for in § 1.265(a)(1). The preexamination search provided for in § 1.265(a)(1) should result in the reference or references that are most closely related to the subject matter of the claims. However, an applicant may not exclude a reference from an examination support document simply because the reference was not the result of the preexamination search provided for in § 1.265(a)(1). The reference, for instance, may have been brought to applicant's attention via a foreign or PCT search report. References that have

46742 Federal Register / Vol. 72, No. 161 / Tuesday, August 21, 2007 / Rules and Regulations

been brought to the applicant's attention regardless of the source of those references must be considered in identifying the reference or references most closely related to the subject matter of each of the claims.

Section 1.265(a)(3) provides that an examination support document must, for each reference in the listing of references required under § 1.265(a)(2), identify all of the limitations of each of the claims (whether in independent or dependent form) that are disclosed by the reference. Applicant may satisfy this requirement either by mapping the limitations of each of the claims to the references or by mapping the references to the limitations of the claims.

Applicants may map the limitations of each of the claims to the references by, for each claim, identifying where the cited references disclose features, showings, or teachings that are relevant to each limitation of such claim.

Applicants may map the references to the limitations of the claims by, for each cited reference, identifying where the reference discloses features, showings, or teachings that are relevant to the limitations of each of the claims.

Section 1.265(a)(3) requires the applicant to identify at least one appearance in the reference (a representative portion) of a specific feature, showing, or teaching for which the reference is being cited. If the feature, showing, or teaching appears in more than one portion of the reference, applicant would not need to specifically point out more than one occurrence.

Applicant, however, should do so where the additional appearance may not be apparent to the examiner and may have some additional significance over its first identified appearance. If an applicant recognizes that a document is relevant for more than one feature, showing, or teaching, the applicant would need to specifically identify each additional feature, showing, or teaching and the portion where the feature, showing, or teaching appears in the document. A mere statement indicating that the entire reference, or substantially the entire reference, is relevant would not comply with § 1.265(a)(3).

Section 1.265(a)(4) provides that an examination support document must include a detailed explanation particularly pointing out how each of the independent claims is patentable over the references cited in the listing of references required under § 1.265(a)(2). The explanation required by § 1.265(a)(4) may be set forth together with the identification required by § 1.265(a)(3) or may be provided separately. For example, the identification required by § 1.265(a)(3)

and the explanation required by § 1.265(a)(4) may be set out in a single spreadsheet with two columns, or may be set out in two spreadsheets. A general statement that all of the claim limitations are not described in a single reference does not satisfy the requirements of § 1.265(a)(4). Section 1.265(a)(4) requires that the examination support document set out with particularity, by reference to one or more specific claim limitations, why the claimed subject matter is not described in the references, taken as a whole. The applicant must explain why a person of ordinary skill in the art would not have combined the features disclosed in one reference with features disclosed in another reference to arrive at the claimed subject matter. The applicant must also explain why the claim limitations referenced render the claimed subject matter novel and non-obvious over the cited prior art.

Section 1.265(a)(5) provides that an examination support document must include a showing of where each limitation of the claims (whether in independent or dependent form) finds support under 35 U.S.C. 112, ¶ 1, in the written description of the specification. If the application claims the benefit of one or more applications under title 35, United States Code; the showing must also include where each limitation of the claims finds support under 35 U.S.C. 112, ¶ 1, in each such application in which such support exists. For means- (or step-) plus-function claim elements under 35 U.S.C. 112, ¶ 6, this requires: (1) That the claim limitation be identified as means- (or step-) plus-function claim element under 35 U.S.C. 112, ¶ 6; and (2) that the structure, material, or acts in the specification that correspond to each means- (or step-) plus-function claim element under 35 U.S.C. 112, ¶ 6, be identified. See *Changes to Practice for Petitions in Patent Applications To Make Special and for Accelerated Examination*, 71 FR at 36325, 1308 Off. Gaz. Pat. Office at 107.

If the examiner, after considering the application and any examination support document, still has questions concerning the invention or how the claims define over the prior art or are patentable, the examiner may request an interview before the first Office action. If the applicant declines such a request for an interview or if the interview does not result in the examiner obtaining the necessary information, the examiner may issue a requirement for information under § 1.105 to obtain such information. Section 1.133(a)(2) was amended in November of 2005 to permit an interview before the first Office

action if the examiner determines that such an interview would advance prosecution. See *Provisions for Claiming the Benefit of a Provisional Application With a Non-English Specification and Other Miscellaneous Matters*, 70 FR at 56121, 56128, 1299 Off. Gaz. Pat. Office at 144, 150. Applicant may request an interview before the first Office action. Such a request is ordinarily granted in a continuing application or if the examiner determines that the interview would advance prosecution. See § 1.133(a)(2) and MPEP § 713.02.

Section 1.265(b) provides that the preexamination search must involve U.S. patents and patent application publications, foreign patent documents, and non-patent literature, unless the applicant can justify with reasonable certainty that no references more pertinent than those already identified are likely to be found in the eliminated source. That justification must be included in the statement required by § 1.265(a)(1). Section 1.265(b) also provides that the preexamination search must encompass all of the limitations of the independent claims. It must also encompass all of the limitations of the dependent claims separately from the claim or claims from which they depend. The claims must be given the broadest reasonable interpretation. A search report from a foreign patent office will not automatically satisfy the requirement in § 1.265(a)(1) for a preexamination search unless it includes the information required by § 1.265.

Section 1.265(c) provides for the content requirements of the listing of references required under § 1.265(a)(2) as part of an examination support document. Section 1.265(c) provides the same content requirements as those that are currently provided in §§ 1.98(a) and (b). Specifically, § 1.265(c) provides that the listing of references required under § 1.265(a)(2) as part of an examination support document must include a list identifying each of the cited references (§§ 1.265(c)(1) and (c)(2)), a copy of each reference except for references that are U.S. patents or U.S. patent application publications (§ 1.265(c)(3)), and each English language translation if required by § 1.265(c)(4). Applicant may use the USPTO form, "Examination Support Document Listing of References," to submit the listing of references. The form will be available on the Office's Internet Web site at <http://www.uspto.gov/web/forms/index.html#patent>.

Section 1.265(c)(1) provides that the list of cited references must group U.S. patents and U.S. patent application publications (including international

applications designating the United States) in a section separate from other references. Section 1.265(c)(1) also provides that each page of the list of the cited references must include: (1) The application number, if known, of the application in which the examination support document is being filed; (2) a column that provides a space next to each cited reference for the examiner's initials; and (3) a heading that clearly indicates that the list is part of an examination support document listing of references.

Section 1.265(c)(2) provides that the list of cited references must identify each cited reference as follows: (1) Each U.S. patent must be identified by first named patentee, patent number, and issue date; (2) each U.S. patent application publication must be identified by applicant, patent application publication number, and publication date; (3) each U.S. application must be identified by the applicant, application number, and filing date; (4) each foreign patent or published foreign patent application must be identified by the country or patent office which issued the patent or published the application, an appropriate document number, and the publication date indicated on the patent or published application; and (5) each publication must be identified by publisher (e.g., name of journal), author (if any), title, relevant pages of the publication, publication date, and place of publication.

Section 1.265(c)(4) provides that if a non-English language document is being cited, any existing English language translation of the non-English language document must be submitted if the translation is within the possession, custody, or control of, or is readily available to any individual identified in § 1.56(c).

Section 1.265(d) provides for a supplemental examination support document. If an information disclosure statement is filed in an application in which an examination support document is required and has been filed, the applicant must also file a supplemental examination support document addressing the references cited in the information disclosure statement in the manner required under §§ 1.265(a)(3) and (a)(4), unless the information disclosure statement cites only references that are less closely related to the subject matter of one or more claims than the references cited in the examination support document listing of references required under § 1.265(a)(2).

Section 1.265(e) provides that the applicant will be notified if: (1) The

examination support document or preexamination search is deemed to be insufficient; or (2) the claims have been amended such that the examination support document no longer covers each claim. The notice will give the applicant a two-month time period within which the applicant must either file a corrected or supplemental examination support document or amend the application such that it contains no more than five independent claims and no more than twenty-five total claims in order to avoid abandonment. Section 1.265(e) further provides that this two-month period is not extendable under § 1.136(a).

Section 1.265(f) provides an exemption from the requirement in § 1.265(a)(3) that an examination support document must, for each reference cited in the listing of references required under § 1.265(a)(2), include an identification of all of the limitations of each of the claims (whether in independent or dependent form) that are disclosed by the reference that applies to applications by a small entity as defined by the Regulatory Flexibility Act (5 U.S.C. 601 *et seq.*). The Regulatory Flexibility Act defines a "small entity" as a "small business" as defined in 5 U.S.C. 601(3), a "small organization" as defined in 5 U.S.C. 601(4), and a "small governmental jurisdiction" as defined 5 U.S.C. 601(5). See 5 U.S.C. 601(6). Section 1.265(f) specifically provides that an examination support document, or a corrected or supplemental examination support document, is not required to comply with the requirements set forth in § 1.265(a)(3) if the examination support document is accompanied by a certification that any rights in the application have not been assigned, granted, conveyed, or licensed, and there is no obligation under contract or law to assign, grant, convey, or license any rights in the application, other than a security interest that has not been defaulted upon, to any entity other than a business or other concern as defined in § 1.265(f)(1), a not-for-profit enterprise as defined in § 1.265(f)(2), or a government as defined in § 1.265(f)(3). A business or other concern which meets the definition set forth in § 1.265(f)(1), a not-for-profit enterprise that meets the definition set forth in § 1.265(f)(2), or a government that meets the definition set forth in § 1.265(f)(3) may make the certification provided for in § 1.265(f) regardless of whether the business or other concern, not-for-profit enterprise, or government is located in or operates primarily in the United States.

With respect to the business or other concerns defined in § 1.265(f)(1), the Regulatory Flexibility Act provides that "the term 'small business' has the same meaning as the term 'small business concern' under section 3 of the Small Business Act, unless an agency, after consultation with the Office of Advocacy of the Small Business Administration and after opportunity for public comment, establishes one or more definitions of such term which are appropriate to the activities of the agency and publishes such definition(s) in the *Federal Register*." See 5 U.S.C. 601(3). The Office has established the standard set forth in 13 CFR 121.802 for paying reduced patent fees as the definition of "small business" for Regulatory Flexibility Act purposes with respect to patent-related regulations. Therefore, a "small business" for Regulatory Flexibility Act purposes with respect to patent-related regulations is a business or other concern: (1) Whose number of employees, including affiliates, does not exceed 500 persons; and (2) which has not assigned, granted, conveyed, or licensed (and is under no obligation to do so) any rights in the invention to any person who made it and could not be classified as an independent inventor, or to any concern which would not qualify as a non-profit organization or a small business concern under this definition.

With respect to the not-for-profit enterprises defined in § 1.265(f)(2), the Regulatory Flexibility Act provides that "the term 'small organization' means any not-for-profit enterprise which is independently owned and operated and is not dominant in its field, unless an agency establishes, after opportunity for public comment, one or more definitions of such term which are appropriate to the activities of the agency and publishes such definition(s) in the *Federal Register*." See 5 U.S.C. 601(4). The Office has not established any definition of "small organization" for Regulatory Flexibility Act purposes with respect to patent-related regulations. Therefore, a "small organization" for Regulatory Flexibility Act purposes with respect to patent-related regulations is a not-for-profit enterprise which is independently owned and operated and is not dominant in its field.

With respect to the governments defined in § 1.265(f)(3), the Regulatory Flexibility Act provides that "the term 'small governmental jurisdiction' means governments of cities, counties, towns, townships, villages, school districts, or special districts, with a population of less than fifty thousand, unless an

agency establishes, after opportunity for public comment, one or more definitions of such term which are appropriate to the activities of the agency and which are based on such factors as location in rural or sparsely populated areas or limited revenues due to the population of such jurisdiction, and publishes such definition(s) in the *Federal Register*.¹⁵ See 5 U.S.C. 601(5). The Office has not established any definition of "small governmental jurisdiction" for Regulatory Flexibility Act purposes with respect to patent-related regulations. Therefore, a "small governmental jurisdiction" for Regulatory Flexibility Act purposes with respect to patent-related regulations is a government of a city, county, town, township, village, school district, or special district, with a population of less than fifty thousand.

An entity that meets the definition of a small entity set forth in § 1.27 for paying reduced patent fees may or may not meet one of the definitions under §§ 1.265(f)(1) through (f)(3) to make a certification under § 1.265(f). The Office will not give advisory opinions as to whether or not a specific individual or entity meets the definitions under §§ 1.265(f)(1) through (f)(3) to make a certification under § 1.265(f). Questions related to standards for small business concerns, not-for-profit enterprises, or governments may be directed to: Small Business Administration, Size Standards Staff, 409 Third Street, SW., Washington, DC 20416.

Section 1.495 (entering the national stage in the United States of America): Section 1.495(g) provides that if the documents and fees contain conflicting indications as to whether the submission is an application under 35 U.S.C. 111 or a submission to enter the national stage under 35 U.S.C. 371, the documents and fees will be treated as a submission to enter the national stage under 35 U.S.C. 371. It is Office experience that, in most cases, documents and fees that contain such conflicting indications were intended as submissions under 35 U.S.C. 371.

Section 1.704 (reduction of period of adjustment of patent term): Section 1.704(c) is amended to provide the patent term adjustment consequences of a failure to comply with § 1.75(b) (e.g., a failure to file an examination support document in compliance with § 1.265 when necessary under § 1.75(b)). Such a failure will be considered a circumstance that constitutes a failure of an applicant to engage in reasonable efforts to conclude processing or examination of an application under 35 U.S.C. 154(b)(2)(C). The failure to comply with § 1.75(b) will delay

processing or examination of an application because the Office must issue a notice and await the applicant's reply before examination of the application may begin. Therefore, § 1.704(c) provides for a reduction of any patent term adjustment when there is a failure to comply with § 1.75(b). Specifically, any patent term adjustment will be reduced by the number of days in the period between the following beginning and ending dates. The beginning date of the period is the day after the date that is the later of: (1) The filing date of the amendment resulting in the noncompliance with § 1.75(b); (2) four months from the filing date of the application in an application under 35 U.S.C. 111(a); or (3) four months from the date on which the national stage commenced under 35 U.S.C. 371(b) or (f) in an application which entered the national stage from an international application after compliance with 35 U.S.C. 371. The ending date of the period is the filing date of: (1) An examination support document in compliance with § 1.265; (2) an election responsive to an Office-issued requirement for restriction including an election of species that places the application in compliance with § 1.75(b) (e.g., the election of an invention that is drawn to five or fewer independent claims and twenty-five or fewer total claims that would obviate the need for an examination support document under § 1.265); (3) an amendment resulting in compliance with § 1.75(b) (e.g., amending the application to contain five or fewer independent claims and twenty-five or fewer total claims); (4) a suggested requirement for restriction under § 1.142(c) accompanied by an election without traverse of an invention to which there are no more than five independent claims and no more than twenty-five total claims.

The examiner's acceptance of a suggested requirement for restriction accompanied by an election without traverse of an invention to which there are no more than five independent claims and no more than twenty-five total claims would be sufficient to obviate the need for an examination support document under § 1.265. If the suggested requirement for restriction is not accepted, the applicant will be notified and given a time period within which the applicant must either file an examination support document or amend the application such that it contains no more than five independent claims and no more than twenty-five total claims. Failure to timely reply to such a notice would result in the

abandonment of the application. The abandonment of an application results in the period of adjustment set forth in § 1.703 (if any) being reduced under § 1.704(c)(3).

III. Response to Comments

As discussed previously, the Office published notices in January of 2006 proposing: (1) Changes to practice for continuing applications, requests for continued examination, and applications containing patentably indistinct claims; and (2) changes to the practice for the examination of claims in patent applications. See *Changes to Practice for Continuing Applications, Requests for Continued Examination Practice, and Applications Containing Patentably Indistinct Claims*, 71 FR at 48–61, 1302 Off. Gaz. Pat. Office 1318–29, and *Changes to Practice for the Examination of Claims in Patent Applications*, 71 FR 61–69, 1302 Off. Gaz. Pat. Office 1329–35. The Office received over five hundred written comments (from government agencies, universities, intellectual property organizations, industry, law firms, individual patent practitioners, and the general public) in response to this notice. The comments and the Office's responses to the comments follow:

A. Changes to Continuing Application Practice

Comment 1: A number of comments stated that the changes in the definitions of continuation, divisional, and continuation-in-part applications set forth in § 1.78(a) are likely to confuse the public and examiners and that the Office has not identified any value that would result from these changes. Several comments suggested that further guidance was needed to resolve ambiguities as to whether an application is a divisional or continuation application. One comment argued that the requirement to identify the relationship of the applications could create hardship when it is unclear whether the changes to the specification or claims make the application a continuation, divisional, or continuation-in-part application.

Response: The definitional changes are necessary in order to clearly define the conditions for claiming benefit of prior-filed applications under § 1.78(d)(1). This final rule further clarifies the definition of a divisional application set forth in § 1.78(a)(2). Under this final rule, an applicant may file a divisional application directed to a non-elected invention if the prior-filed application is subject to a requirement for restriction. The divisional application need not be filed during the

pendency of the application subject to a requirement for restriction, as long as the copendency requirement of 35 U.S.C. 120 is met. Thus, applicant may file a divisional application claiming the benefit of the initial application that was subject to the requirement for restriction and any intermediate continuing applications.

Furthermore, the definitions of continuation, divisional, and continuation-in-part application set forth in § 1.78(a) are substantially the same as the previous definitions set forth in the MPEP, except that a divisional application is now defined more narrowly. See the discussion of § 1.78(a). The former practice permitted an applicant to file a continuing application and identify the application as a "divisional" application even when the prior-filed application was not subject to a requirement for restriction. Such a continuing application was called a "voluntary" divisional application. Under this final rule, a "voluntary" divisional application would instead fall under the definition of a continuation application. Therefore, a continuing application would be a continuation application and not a divisional ("voluntary" divisional) application if the prior-filed application was not subject to a requirement for restriction. If the prior-filed application was subject to a requirement for restriction, a continuing application claiming only a non-elected invention or inventions would be a divisional application. It is noted that although the definition of continuation application set forth in § 1.78(a)(2) uses the phrase "invention or inventions" rather than "subject matter" (as used in the definition of continuation application set forth in MPEP § 201.07), no substantive difference between these terms is intended. The requirement to identify the relationship (*i.e.*, continuation, divisional, or continuation-in-part) between the prior-filed application and the continuing application is not a new requirement under this final rule. This requirement has been provided in the former § 1.78(a)(2)(i). Accordingly, the definitions of continuation, divisional, and continuation-in-part application set forth in § 1.78(a) are not likely to confuse the public or examiners for any extended period.

Comment 2: A number of comments observed the proposed requirement that a divisional application may claim the benefit of only a single application would require that all divisional applications filed as a result of a restriction requirement in a prior-filed application be filed before the patenting

or abandonment of that application. A number of comments suggested that the rule changes limiting divisional applications to claim benefit to only a single prior-filed application would result in an overall increase in application filings and pendency, contrary to their intended purpose. The comments contended the changes being adopted in this final rule effectively force applicants to claim all patentably distinct inventions in the prior-filed application or file related applications in parallel in order to preserve potential patent rights in those inventions. The comments suggested that since a divisional application must be filed during the pendency of the prior-filed application, many more divisional applications would be filed than would be filed under the current system, as applicants will not have sufficient time and information to determine whether the invention is worth pursuing. The comments stated that, consequently, the Office will be forced to examine more inventions than it would under current practice, wasting both applicants' and the Office's resources. A number of comments also suggested that the inability to prosecute divisional applications sequentially, thus allowing applicants to spread filing and prosecution costs over time and to file only those divisional applications that are commercially valuable in view of subsequent market development, will have a particularly negative impact on the biotechnology and pharmaceutical industries and on small entities. The comments suggested that patent rights will be lost due to a lack of funding and that the increased costs will be particularly onerous in certain technologies, *e.g.*, biotechnology and chemical arts, where the Office routinely issues complex restriction requirements, sometimes alleging hundreds or thousands of independent and distinct inventions. Several comments also suggested that the rules should be modified to account for the economic impossibility, in many cases, of pursuing numerous divisional applications simultaneously. One comment also suggested that the need to file multiple stand alone applications or divisional applications at an early stage in prosecution to cover all embodiments of the invention will cause small companies to cut back funding on research in favor of patent prosecution, thus hindering innovation. One comment also suggested that the rules be revised, consistent with European Patent Office divisional practice, to permit the serial filing of divisional applications with the limitation that

claims pursued in a continuation of any serial divisional application must be of the same scope as, or of a narrower scope than, the claims presented in that serial divisional application. One comment also suggested that prior to implementing the rule changes, the Office should conduct a study to assess the scope of potential divisional filing problems by studying the divisional filing habits of large and small entity applicants.

Response: The Office notes the concerns expressed in the public comment regarding the proposed requirement in § 1.78(d)(1)(ii) that a divisional application be filed during the pendency of the initial application. In response to those concerns and suggestions, § 1.78(d)(ii) as adopted in this final rule does not require that a divisional application be filed during the pendency of the initial application. This final rule permits applicants to file a divisional application for the claims to a non-elected invention if the initial application is subject to a requirement for restriction, the claims to the non-elected invention are cancelled in the initial application, and the divisional application meets the copendency requirement of 35 U.S.C. 120. That is, an applicant may file a divisional application during the pendency of the application that was subject to a restriction requirement or the pendency of any continuing application of such application. This final rule also permits applicant to file two continuation applications of a divisional application, plus a request for continued examination in the divisional application family, without any justification.

Comment 3: A number of comments suggested that the rule changes would encourage applicants to file more petitions challenging restriction requirements, thus further burdening the Office.

Response: The criteria for making a restriction requirement remain the same. Applicant may still seek review of any restriction requirements, if appropriate. The Office, however, does not anticipate any substantial increase in the number of petitions seeking review of restriction requirements. As discussed previously, § 1.78(d)(1)(ii) as adopted in this final rule does not require that a divisional application be filed during the pendency of a single prior-filed application. This final rule permits applicant to file a divisional application of an application if the application is subject to a requirement for restriction, claims to the non-elected invention are cancelled in the prior-filed application, and the divisional

application meets the copendency requirement of 35 U.S.C. 120. That is, applicant may file a divisional application during the pendency of the application that was subject to a requirement for restriction or the pendency of any continuing application of such application. Applicant will have sufficient time to determine whether to file a divisional application directed to a non-elected invention.

Comment 4: Several comments stated that the rule changes do not adequately address the situation where a restriction requirement is made by the examiner in a continuing application. The comments expressed concern that the rule changes appear to require applicant to forego all but one invention. One comment stated that the applicant's prior application, if published, may constitute prior art if benefit to the prior application is not permitted. Another comment suggested that concerns over prolonging patent term, abuse or bad faith are not raised where a divisional application is filed as a result of a restriction requirement made in the continuing application, and that such filings may actually improve quality, as the searches performed in the initial and first continuing application often provide significant information and guidance to the examiner in the second continuing application.

Response: As discussed previously, the Office has modified the proposed § 1.78(d)(1)(ii) in this final rule such that it does not require a divisional application to be filed during the pendency of a single prior-filed application. Instead, this final rule permits an applicant to file a divisional application for the claims to a non-elected invention that was not examined if the application was subject to a requirement for restriction, the claims to the non-elected invention are cancelled in the prior-filed application, and the divisional application meets the copending requirement of 35 U.S.C. 120. Therefore, applicant may file a divisional application of a continuing application for the claims to a non-elected invention that has not been examined if the continuing application was subject to a requirement for restriction. Such a divisional application may claim the benefit of the continuing application that was subject to a requirement for restriction and the initial application whose benefit is claimed in the continuing application.

Comment 5: One comment requested clarification as to whether a divisional application can be filed if a request for continued examination was filed in the initial application.

Response: The filing of a request for continued examination in the initial

application does not preclude an applicant from filing a divisional application under the proposed rule as well as under this final rule. The condition that "no request for continued examination under § 1.114 has been filed in the prior-filed application" as proposed applied only to the filing of continuation and continuation-in-part applications under proposed § 1.78(d)(1)(i). Compare proposed §§ 1.78(d)(1)(i) and 1.78(d)(1)(ii). Furthermore, § 1.78(d)(1) as adopted in this final rule contains no conditions with respect to continuation applications, divisional applications, or continuation-in-part applications concerning whether a request for continued examination was filed in the initial application or a prior-filed continuing application. Therefore, the filing of a request for continued examination does not preclude an applicant from filing two continuation or continuation-in-part applications, and any divisional application directed to a non-elected invention that has not been examined if the prior-filed application was subject to a requirement for restriction.

Comment 6: A number of comments requested that the Office not limit "voluntary" divisional applications. In addition, several comments noted the importance of "voluntary" divisional applications in protecting important inventions the significance of which could not reasonably be anticipated when the application was filed. Another comment indicated the importance of "voluntary" divisional applications for obtaining quick patents to protect applicants' products from competitors while preserving the opportunity to obtain patent protection on other aspects of the invention. Several comments stated that the standard under § 1.78(d)(1) makes little sense when the objective of filing the continuing application is to obtain patents on distinct inventions. One of the comments expressed concern that each patent is, both by law and regulation, to be directed to a single invention and that patent applications directed to multiple inventions are subject to restriction under 35 U.S.C. 121.

Response: This final rule permits applicants to file a so-called "voluntary" divisional application as a continuation application in compliance with § 1.78(d)(1)(i) when the prior-filed application was not subject to a requirement for restriction. Under § 1.78(d)(1)(i), applicant may file two such continuation applications without a petition and showing of why the amendment, argument, or evidence

sought to be entered could not have been previously submitted. Applicant likewise may file a third or subsequent continuation application with a petition and showing pursuant to § 1.78(d)(1)(vi).

Furthermore, applicant may suggest a requirement for restriction under § 1.142(c) if the applicant believes that two or more independent and distinct inventions are claimed in the application. See § 1.142(c) and the discussion of § 1.142(c). In such case, § 1.78(d)(1)(ii) provides that an applicant may file a divisional application directed to a non-elected invention that has not been examined if the prior-filed application is subject to a requirement for restriction. The divisional application is not required to be filed during the pendency of the application subject to a requirement for restriction, as long as the copendency requirement of 35 U.S.C. 120 is met. Section § 1.78(d)(1)(iii) also permits an applicant to file, without a petition and showing, two continuation applications of a divisional application plus a request for continued examination in the divisional application family. Therefore, applicants have sufficient opportunity to obtain patent protection on other aspects of the invention.

35 U.S.C. 121 provides that "[i]f two or more independent and distinct inventions are claimed in one application, the Director may require the application to be restricted to one of the inventions." (Emphasis added.) Thus, 35 U.S.C. 121 authorizes, but does not compel, the Director to require that an application containing two or more independent and distinct inventions be restricted to one of the inventions. The Office typically decides whether to issue a restriction requirement when an application contains two or more independent and distinct inventions based upon, *inter alia*, the burden on the Office to search and examine more than one invention. See MPEP § 803.

Comment 7: Several comments suggested that the restriction on a so-called "voluntary" divisional application would be a major divergence from other countries and would not be favorable from the viewpoint of promoting global harmonization of patent practices. One comment noted that the Japan Patent Office (JPO) and the European Patent Office (EPO) have liberal "voluntary" divisional application rules and have not reported any evidence of abuse.

Response: Under this final rule, applicant still has the opportunity to file a so-called "voluntary" divisional application except that such an application is defined in this final rule